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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,691	11/26/2003	Karl Reinitz	0121	6148
32366	7590	11/02/2006	EXAMINER	
BRUCE E. WEIR 12 SPARROW VALLEY COURT MONTGOMERY VILLAGE, MD 20886-1265			FOSTER, MARLEE CHRISTINE	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/721,691	REINITZ, KARL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Marlee C. Foster	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 6, 7, 10, 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Hill et al. (US Patent 7,122,040). Hill et al. disclose a suturing apparatus comprising a body, a needle having a proximal and distal end, the distal end of the needle having a tip capable of penetrating tissue, a moveable arm, and a moveable arm actuator that contacts the tip of the suture needle (see figure 10). The moveable arm can be actuated to a closed position or an open position. Hill et al. disclose a needle in figure 7B with a J-shape or hook shape. The distal end of the needle has a passage to hold the suture material. The moveable arm actuator comprises a compression member, disclosed as a spring in col. 4, lines 10-12, which acts to move the arm to a closed or open position.

Regarding claims 10 and 11, Hill et al. further disclose a first depression and a second depression, shown in figure 6, disposed on the opposite sides of the body and underside of the body.

3. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Gimpelson (US Patent 5,336,239). Gimpelson discloses a suture needle comprising a suture

passage, a member that covers the needle tip to protect the suture means, and a means for engaging the suture means. See figures 3D-3I.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gimpelson (US Patent 5,336,239) in view of Forde (US Patent 2,692,415).

Gimpelson discloses a suturing device (10) with a body (40), a J-shaped needle (28), a moveable arm (44) used to cover the sharpened tip of the needle, and a passage (34) in the needle to hold the suture. Gimpelson fails to teach a moveable arm that is pivotably mounted to the body of the device, and actuated by a spring.

6. Forde teaches a device with a needle (10) and a moveable arm pivotably mounted to the body of the needle (17). Forde discloses a spring in the body that actuates movement of the arm (col. 1, lines 10-14). Forde additionally discloses a semi-circular sheath (25) that contacts and holds the tip of the needle. Forde teaches the motivation for the sheath design is to hold the needle in a safety position so that it can be exposed only when it is required for use.

7. Therefore, it would have been obvious to one of ordinary skill in the art to combine the features of the device of Forde with the device of Gimpelson in order to

protect the surrounding tissue from the sharp tip of the needle, and provide an actuator that is easy for the user to operate.

8. Claims 4, 5, 8, 9, 13, 14, 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US Patent 7,122,040), in view of Kirk III, et al. (US Patent 5,151,089), hereinafter "Kirk". Hill et al. disclose a suturing apparatus with a moveable arm, moveable arm actuator, and a needle with a hook or J-shape, and a first depression and a second depression, shown in figure 6, disposed on the opposite sides of the body and underside of the body. However, Hill et al. lack the moveable arm pivotally mounted about the body. Hill et al. are also silent as to the material composition of the device. Kirk discloses a body, a needle, and a retractable pivotable arm (reference 11, figure 7) that acts as a protective sheath for covering the tip of the needle to avoid accidental penetration of tissue.

Regarding claims 8 and 14, Kirk discloses the device composed of a material that will permit sterilization (col. 5, lines 58-60). It is well known in the art to manufacture surgical instruments from compositions that are capable of tolerating the temperatures of autoclave sterilization.

Regarding claims 9 and 16, Kirk discloses a handle attached to opposite sides of the body. This handle could presumably be used by one hand.

Therefore, it would have been obvious to one of ordinary skill in the art to provide the device of Hill et al. with the features taught by Kirk of a protective arm, a handle attached to opposite sides of the body, and an instrument that will tolerate autoclave sterilization.

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9. Claims 12 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. (US Patent 7,122,040) in view of Kirk (US Patent 5,151,089), and in further view of Hasson (US Patent 5,628,757). Hill et al. disclose a trigger like handle, with grooves shown to provide a better grip, and Kirk discloses a simplified handle disposed on opposite sides of the body. The invention of Hasson combines the features of the handles of Hill et al. and Kirk, and teaches two members (Figure 3, 104 and 106), each disposed on opposite sides of the body. The second member (106) teaches depressions on the opposite sides located on the underside of the handle (col. 7, lines 5-10). Hasson teaches this design facilitates ambidextrous gripping of the device, that is, by either the right or left hand (col. 7, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art to modify the design of Hill et al. and Kirk with the features of Hasson to enable the device to be easily gripped with only one hand.

### ***Response to Arguments***

10. Applicant's arguments, filed September 25, 2006, with respect to the rejection(s) of claim(s) 1-19 under Rioux and Greenstein have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the devices of Hill et al. and Gimpelson cited in this office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marlee C. Foster whose telephone number is (571) 272-5072. The examiner can normally be reached on Monday to Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Marlee C. Foster  
Patent Examiner  
Art Unit 3731



ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

10/28/06